

Taking Relationships as Seriously as Science

COMPLEX THERAPEUTIC AREAS AND STUDY DESIGNS



MEDSOURCE

FEATURED SERVICES

MedSource is an award-winning clinical research organization (CRO) that provides trusted support for oncology and other complex clinical trials. Whether tackling a challenging therapeutic area or developing a sophisticated trial design, our experienced team uses strong relationships to deliver high-quality clinical trials.

STUDY STARTUP

- Feasibility analysis and report
- Site identification, recruitment and qualification
- Site contracts and investigator payments
- Investigator meeting planning
- Site regulatory document collection and management

PROJECT MANAGEMENT

- Overall study management
- Budget and timeline tracking
- Customized weekly, monthly and quarterly reporting
- Vendor management

CLINICAL TRIAL MONITORING

- Site initiation, interim monitoring and close-out visits
- CRA oversight
- Site management
- Query resolution
- Clinical site coordinator support

REGULATORY AFFAIRS MANAGEMENT

- Regulatory applications and submissions
- Clinical quality assurance audits
- Trial master file and eTMF management
- Strategic regulatory guidance
- Tactical regulatory support

DATA MANAGEMENT AND BIOMETRICS

- CRF design
- Randomization
- Statistical design and analysis
- Data management and cleaning
- EDC management
- Medical writing

SAFETY

- Pharmacovigilance
- Medical monitoring
- DSMB
- Comprehensive case management

CLINICAL SUPPORT SERVICES

- Central lab, imaging and histology vendor management
- Drug and trial supply management
- Clinical technology solutions
- Global trial management

By focusing on our core service offerings, we exceed expectations with superior results.



MEDSOURCE

Trust.
Respect.
Transparency.
Peace of Mind.

If these aren't words you typically associate with a CRO, perhaps it's time you consider MedSource. At MedSource, we take relationships as seriously as science.

Our People

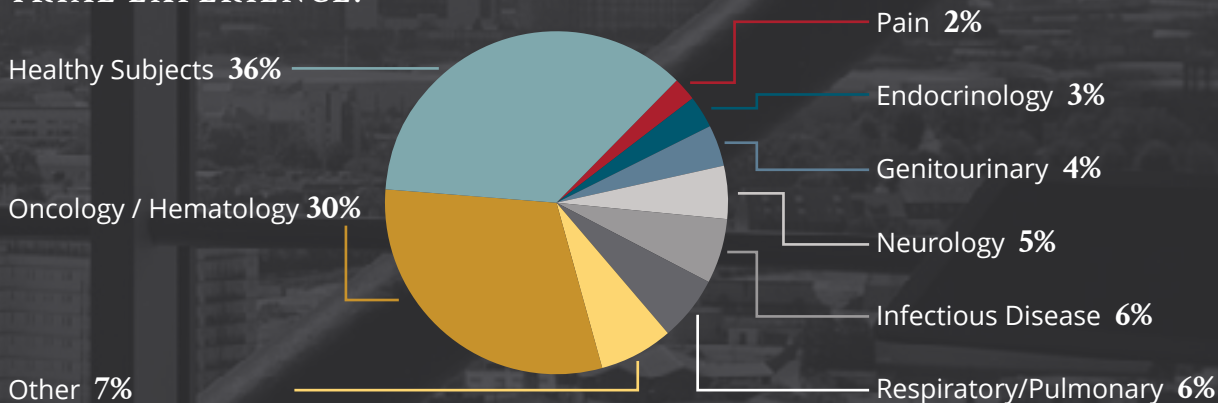
By bringing stability and experience to your project, our employees deliver results with consistency.

We take great pride in being selective and choosing the right people to join the MedSource team. Every project presents unique challenges. We attract, retain and value experienced problem solvers who can adapt to the unique challenges of each project. Our employees must have the ability to listen, understand and assess the situation; devise, plan and implement the most effective solution; and most importantly, achieve the desired results.

ONGOING TRAINING

We help our staff advance their skills through ongoing training and professional development. This regularly includes good clinical practice (GCP) training, therapeutic-specific overviews, conferences, web-based teleconferences, industry-recognized continuing education seminars, and subscriptions to industry publications and handbooks. With our background and experience enhanced by training on the latest industry developments, we can ensure our team has the expertise needed to deliver the highest quality and innovative clinical trial execution.

TRIAL EXPERIENCE:



A BALANCED PERSPECTIVE

Our clients trust that we will get the job done with minimal management required. Our teams are passionate, genuine and critically focused on integrity and results. The team you meet at the start is the team that works on your project. We are committed to ensuring your projects have an experienced, cohesive and stable project team throughout the project life cycle. We are candid about all our processes, and we provide line-item bids, so you see everything up front.

ONCOLOGY EXPERTISE

We have experience across a broad range of therapeutic areas, clinical trial phases and study designs, but have a particular expertise in studies that involve challenging diseases, such as oncology, infectious diseases and CNS studies with complex designs. We have participated in more than 700 clinical trials globally. Of our therapeutically focused studies, more than 60% of those clinical trials were in oncology. Our efforts support biopharmaceutical clients that conduct complex trials in the most challenging disease states.

ONCOLOGY SPECIFIC EXPERIENCE:

Hematology/Leukemia/Lymphoma **30%**

Genitourinary (GU) **19%**

Other/Supportive **12%**

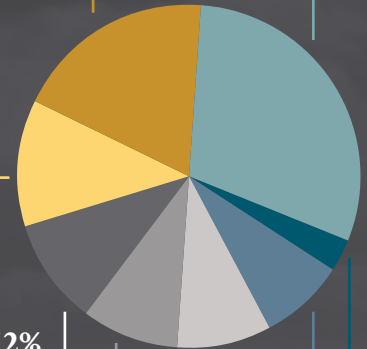
Lung/Thoracic **10%**

Breast **9%**

Other Advanced Solid Tumors **9%**

Gastrointestinal (GI) **8%**

Gynecological **3%**





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